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DIPLOMATE, AMERICAN BOARD OF
INTERNAL MEDICINE (RECERTIFIED)

'99 APR -9 A9:22

April 7, 1999

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1051
Rockville, MD 20852

re: Food Additive Petition by Monsanto
(Docket No. 99F-0187) for Neotame

Dear sirs,

You have received my previous letters of March 3, 1998 and February 25, 1999, expressing my extreme professional opposition to the approval of Neotame as an all-purpose sweetener (copies of both are enclosed) without further data.

This correspondence is prompted by my analysis of Monsanto's "Environmental Assessment," dated December 17, 1998, which I have just read today. I am troubled by its

99F-0187 C1

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shortcomings, based on my 15-year interest and researches on its analog, aspartame. In view of the deadline of April 10, 1999, I am writing my criticisms as a supplement to my prior letters. They only can be summarized here.

I. Environmental Impact

I believe that there is a potentially significant impact that cannot be necessarily shown by the rat and dog studies, or in the extremely short (13 weeks) tests on healthy subjects.

Contrary to the Monsanto submission, I have considerable data that point to aspartame being toxic, metagenic, carcinogenic, diabetogenic and teratogenic. These assertions

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stem in part from the experience of over 1,200 (!) aspartame reactors in my own data base.

II. Animal Testing

It is a gross error to project the animal studies onto humans when the massive consumption of this chemical is envisioned. (Currently, over half the population consumes aspartame products.) For example, these species metabolize phenylalanine 4-5 times faster than humans. Moreover, phenylalanine concentrates much more on the fetal side of the placenta, and readily crosses the blood-brain barrier to affect the fetus brain.

Comparable arguments could be made for aspartic acid and methanol, which I have addressed in many publications.

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IV. Diabetics

The assertion that aspartame/neotame does not affect glycemic control is WRONG! As a Board-certified internist and endocrinologist, I have repeatedly found that aspartame produces aggravate both diabetes control and its complications - and have written on this subject. My request of corporate-sponsored researchers in this realm to justify by their published "negative" conclusions have not been answered.

V. "Small Amounts"

It is erroneous to assume that "a dietary concentration of less than 10 ppb of each minor degradant..." is innocuous. From my work on pesticides, there are several molecules in each cell even in parts per trillion.

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CONCLUDING COMMENTS

I am a totally corporate-neutral physician who is concerned about the ongoing exposure of the population to aspartame and numerous other chemicals that were approved without adequate long-term pertinent studies by corporate-neutral investigators and politically neutral regulators.

Let me repeat: it will be a public health tragedy if the aspartame problem is allowed to be repeated in the absence of these safeguards!

Yours truly,

H. J. Roberts, M.D.

2 Enclosures

cc: Ms. Blondell Anderson
Center for Food Safety and Applied Nutrition (HFS-206)
FDA, 200 C Street, SW, Washington, DC 20204

Ms. Laura M. Tavantino
Office of Premarket Approval
Center for Food Safety and Applied Nutrition (HFS-206)
FDA, 200 C Street, SW, Washington, DC 20204

Senator Bob Graham
524 Hart Senate Office Building
Washington, D.C. 20510

Representative F. Clay Shaw, Jr., M.C.
222 Lakeview Ave., Suite 162
West Palm Beach, FL 33401

Representative Mark Foley, M.C.
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DIPLOMATE, AMERICAN BOARD OF
INTERNAL MEDICINE (RECERTIFIED)

March 3, 1998

Dockets Management Branch (HFA A-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Subject: Docket No. 98F-0052 (Food Additive Petition for Neotame) .

Dear Sir:

I am writing to express my *EXTREME* opposition to approving the Food Additive Petition for Neotame submitted by Monsanto Company.

It is my professional opinion that this chemical poses a potential major health and environmental hazard to the American public -- particularly in the absence of extensive, detailed and long-term animal and human studies (which I have been unable to obtain) that could prove its safety to my satisfaction. I am a Board-certified internist, and have been the unsalaried director of the Palm Beach Institute for Medical Research (not-for-profit) since 1964.

This opinion is based on more than a decade of intense, corporate-neutral clinical and epidemiological research concerning the widespread serious medical problems directly attributable to products containing aspartame (NutraSweet®, Equal®). My own database currently exceeds 1,150 reactors. I have documented these reactions in more than a score of published articles and letters, and three books.

The fundamental issue is that Neotame, a synthetic variation of aspartame, requires extensive evaluation before the FDA should accept a superficial opinion about its purported safety based largely on limited short-term data involving potentially flawed protocols that were almost totally funded by corporate contracts. (For perspective, I have not received a cent of industry money for my researches.) This matter is discussed at length in my publications relative to both animal and human studies.

The timing and self-serving corporate interests of this petition are suggested by the fact that the patent on aspartame expired several years ago.

The approval of any analog of aspartame for human use MUST be challenged. In my opinion, there is already sufficient evidence for aspartame products to be withdrawn from the market as *an "imminent public health hazard" NOW!* I have documented severe neurological, intellectual, psychiatric, metabolic, endocrine, allergic and other reactions to aspartame products in hundreds of patients. Moreover, there is considerable reason to invoke aspartame and its metabolites as a cause or significant contributory factor in the aggravation or precipitation of diabetes and its complications, multiple sclerosis, brain cancer (see enclosed peer-reviewed article), and the acceleration of Alzheimer's disease (refer to my book *Defense Against Alzheimer's Disease*). I summarized these perceived hazards in previous correspondence to Representative Newt Gingrich (copy enclosed) requesting a new Congressional hearing on the safety of aspartame products.

As a physician and citizen, I am appalled at the thought of American consumers being again subjected to an anticipated repeat of the aspartame fiasco without adequate objective and corporate-neutral evaluations that the FDA ought to DEMAND before taking such an action. It is my longstanding belief that aspartame (originally developed as a drug for treating peptic ulcer) should not have been approved for human consumption in the first place ...a view shared by other professionals (including former in-house FDA scientists, consultants for the General Accounting Office, and a Public Board of Inquiry).

The FDA, other regulatory officials and producers of Neotame products are urged to heed these constructive warnings coming from a credentialed doctor. Concomitantly, they are put on notice that ignoring them will not go unchallenged if proven correct.

Yours truly,

H. J. Roberts, M.D.

H. J. Roberts, M.D., F.A.C.P., F.C.C.P.

Enclosures
- Letter to Representative Newt Gingrich
- List of Roberts publications on aspartame reactions
- Dr. H. J. Roberts' Statement for 1987 Senate Hearing
- Brain cancer article
- Brochure on Alzheimer's disease book
- "Best Doctor"

cc: Ms. Blondell Anderson
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FDA, 200 C Street, SW, Washington, DC 20204

Ms. Laura M. Tavantino
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Senator Bob Graham
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Washington, D.C. 20510

Representative Newt Gingrich, M.C.
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Marietta, GA 30062

Representative F. Clay Shaw, Jr., M
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DIPLOMATE, AMERICAN BOARD OF
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February 25, 1999

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re Food Additive Petition for Neotame [Federal Register, Volume 64, #25, Page 6100]

Dear Sirs,

I submitted the enclosed opposition to the approval of Neotame on March 3, 1998 — and assume you have considered and published (or will publish) it. It is a professional statement reflecting my great concern over the public-health ramifications if this chemical is approved as a general use sweetener — coupled with much additional evidence obtained in the interim.

H. J. Roberts, M.D., F.A.C.P.

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1 From

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H. J. Roberts, M.D.

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